



## RESIDUAL SOLVENTS STATEMENT

### D-Galactose Plant Derived GMP

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the D-Galactose Plant Derived, Bio Excipient Grade manufactured by BioSpectra complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

BioSpectra uses the Class 3 solvent Isopropyl Alcohol in the manufacturing process of D-Galactose Plant Derived, Bio Excipient Grade, and adheres to the specification of  $\leq 5000$  ppm. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program, and can state that the Class 2 solvent Methanol is used in the manufacture of the D-Galactose raw material supplied to BioSpectra, with the material conforming to the specification of <3000ppm. BioSpectra analyzes D-Galactose Plant Derived annually for residual solvents, with results meeting the specifications of NMT 100 ppm Methanol, and NMT 5000 ppm Isopropyl Alcohol. D-Galactose Plant Derived, Bio Excipient Grade is additionally analyzed for residual solvents as detailed in the Certificate of Analysis for the specific product code purchased.

Current Product Number
GALP-3250
GALP-3251
GALP-3252
GALP-3350
GALP-3351

For further information, please contact [info@biospectra.us](mailto:info@biospectra.us)

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